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Abstract

The permanency of corneal reshaping in light of an undesirable outcome has been a major concern for practitioners and patients alike. Therefore, a non-surgical modality that can provide stable and reversible, vision correction has been the ultimate goal of the eye care industry. Corneal reshaping with contact lenses has steadily increased, culminating in the birth of modern Corneal Refractive Therapy or CRT. The Paragon CRT lens is the result of years of ongoing research into the science of overnight corneal reshaping with RGP lenses. This has been made possible by recent merging technologies. In our study, we investigated the success rate of the initial suggested CRT diagnostic lens projected by the Paragon CRT Calculator. Due to the classified nature of the study, the sponsor Paragon Vision Sciences has requested the work remain proprietary until the spring of 2003.

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Degree Name

Master of Science in Vision Science

Committee Chair

Pat Caroline

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PARAGON CRT INITIAL DIAGNOSITC LENS SUCCESS RATE

By

BERNARD KIM
RICHARD YOO

December 16, 2002

A thesis submitted to the faculty of the
Pacific University College of Optometry
Forest Grove, Oregon
For the degree of Doctor of Optometry
May 2003

Advisor:
Pat Caroline

A stylized, handwritten signature in black ink, featuring a large, sweeping 'R' and 'Y'.

Richard Yoo

Bernard Kim

Advisor:

A handwritten signature in black ink, appearing to read 'Pat Caroline' in a cursive script.

Pat Caroline

Biography

Bernard Kim

Pacific University Class of 2003

Bachelor of Science

Visual Science Major

University of Alberta (1995-1999)

Bernard loves God and all sports. His passion is soccer or football as the rest of the world calls it. His parents live in Edmonton, Alberta and has two younger brothers. Bernard is a former child chess prodigy and currently has a red belt in Tae-Kwon-Do. He is a native Canadian and he plans to return to Canada after graduation.

Richard Yoo

Pacific University Class of 2004

University of Oregon (1995-1999)

Bachelor of Arts

General Science Major

Biology, Business, Chemistry Minors

Rich was born in Seoul, South Korea. He moved America when he was five with his parents and older sister and brother. He loves to relax by watching college athletics; nothing better than college football. One of Rich's life goals is to attend his dream school, University of Michigan, and become a true Wolverine. His short term goals after graduation are to gain weight and get a decent haircut.

Acknowledgements

We would like to thank Pat Caroline.
We would also like to thank the people at Paragon Vision Sciences.

Abstract

The permanency of corneal reshaping in light of an undesirable outcome has been a major concern for practitioners and patients alike. Therefore, a non-surgical modality that can provide stable and reversible, vision correction has been the ultimate goal of the eye care industry. Corneal reshaping with contact lenses has steadily increased, culminating in the birth of modern Corneal Refractive Therapy or CRT. The Paragon CRT lens is the result of years of ongoing research into the science of overnight corneal reshaping with RGP lenses. This has been made possible by recent merging technologies. In our study, we investigated the success rate of the initial suggested CRT diagnostic lens projected by the Paragon CRT Calculator. Due to the classified nature of the study, the sponsor Paragon Vision Sciences has requested the work remain proprietary until the spring of 2003.

Introduction to Corneal Refractive Therapy

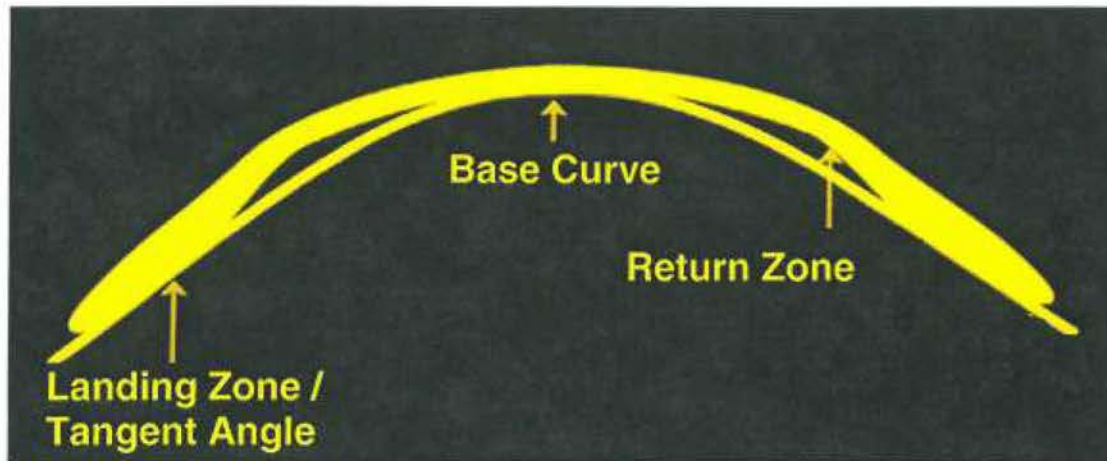
For the past 20 years, visual scientists have struggled with the challenge of providing myopic patients with stable, uncorrected visual acuity throughout the day. Recent advances in refractive surgery have clearly shown that corneal reshaping is possible however; the permanency of these procedures (especially in light of an undesirable outcome) has been a major concern for practitioners and patients alike. Therefore, a non-surgical modality that can provide stable and reversible, vision correction has been the ultimate goal of the eye care industry.

Throughout the years, our knowledge and understanding of corneal reshaping with contact lenses has steadily increased, culminating in the birth of modern Corneal Refractive Therapy or CRT. The Paragon CRT lens is the result of years of ongoing research into the science of overnight corneal reshaping with RGP lenses. This has been made possible by the recent merging of five technologies that include;

1. Advances in unique, multicurve RGP lenses specifically designed to facilitate the safe redistribution of corneal tissue while sleeping thereby correcting many myopic refractive errors.
2. Advances in computer controlled lathing technology allowing these complex lens designs to be consistently fabricated on a level measured in microns.
3. The development of stable, wettable high Dk materials that can be safely worn for overnight corneal therapy.
4. Advances in computerized corneal mapping techniques providing more precise fitting and follow-up of patients.
5. A greater understanding of how corneal reshaping works and the tissues involved in the process.

The Design of the CRT Lens

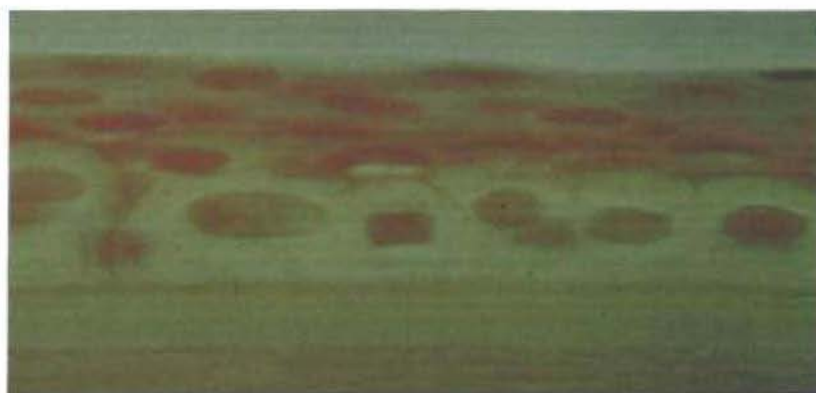
The Paragon CRT lens consists of three primary zones: base curve, return zone and landing zone. A central base curve radius provides the “mold” for the final corneal shape necessary to correct the refractive error.



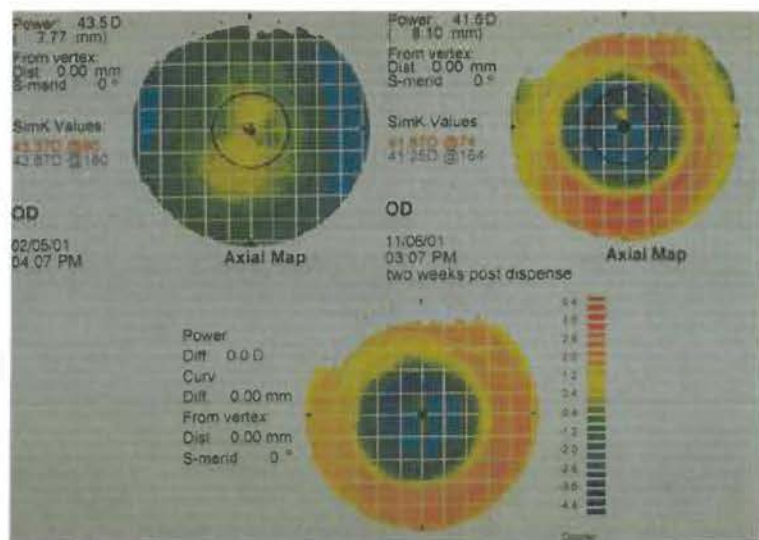
This flatter radius of curvature is also instrumental in creating the appropriate forces beneath the lens to facilitate the movement of corneal tissue. Adjacent to the base curve is a patented sigmoid shaped curve (return zone) which controls the amount of lens clearance across the central cornea. A shallower sigmoid brings the base curve into closer apposition to the cornea, whereas deeper sigmoid results in greater apical clearance. The final design feature is a unique tangent (straight line) angle which provides an appropriate landing zone across the peripheral cornea. The tangent angle terminates in a controlled edge ellipse designed to maximize patient comfort.

How the Paragon CRT Lens Works

The Paragon CRT Lens consists of a complex series of curves and angles specifically designed to optimize the controlled redistribution of corneal tissue during over night lens wear. Recent studies by Swarbrick in 1998 and by Alharbi in 2001 have shown that the topographical changes taking place beneath corneal reshaping lenses are predominately epithelial. Histologic studies had shown that the human epithelium is approximately 50 microns thick.



Half the thickness of the epithelium is made up of the basal cells which remain immobile, firmly attached to Bowmans layer by a complex series of anchors (hemidesmosomes). This appears to indicate that there is between 20 to 25 microns of extremely mobile wing and surface cells available for redistribution. The controlled redistribution of epithelium can be indirectly visualized by viewing the Difference Display Map of the Humphrey Atlas Topographer. This display allows the practitioner to compare the pre-fitting topography with the post-fitting topography while a third (lower) color coded map illustrates the corneal changes that have taken place both centrally and mid-peripherally.



Diagnostic Dispensing System

Paragon CRT lenses are best fitted from an inventory system that allows lenses to be dispensed to the patient at the initial visit. This feature significantly reduces chair time and allows the patient to begin the modality immediately. The actual fitting is a simple three step process.

Step #1 Base Curve Selection

Keratometric readings are obtained by either a manual technique or the simulated "K" from the Humphrey corneal topographer. The Flat "K" and the spherical component of the refractive error (vertexed to the plane of the cornea) are identified and entered into the Paragon CRT Calculator. The Calculator then determines:

1. the base curve radius required to "mold" the epithelium into the necessary shape to correct the refractive error.
2. the initial suggested diagnostic lens to place on the patients eye.

CRT Parameters Available

BASE	RZD	LZA	OAD
7.20			
7.30			10.5
7.40		31	
7.50		32	
7.60		33	
7.70	0.475	34	
7.80	0.500	35	
7.90	0.525		
8.00	0.550		
8.10	0.575		
8.20			
8.30			
8.40			
8.50			
8.60			
8.70			
8.80			
8.90			
9.00			
9.10			
9.20			
9.30			
9.40			
9.50			
9.60			
9.70			
9.80			
9.90			
10.00			
10.10			

Best RZD-LZA Calculator

Right Eye

Flat K	Sphere	TGT
44.50	-4.50	0.00

Left Eye

Flat K	Sphere	TGT
44.50	-4.50	0.00

Right Eye Results:

Rx	0.50
BC	8.60
RZD	0.550
LZA	-34
OAD	10.5

Left Eye Results:

Rx	0.50
BC	8.60
RZD	0.550
LZA	-34
OAD	10.5

TYPE THIS into Database Next Sheet

	R	PH100	Rx	BC	RZD	LZA	OAD
R	PH100	0.50	8.60	0.550	-34	10.5	
L	PH100	0.50	8.60	0.550	-34	10.5	

Table Below For Reference Only

FK	<41.50	42.50	43.25	43.75	44.25	45.25	45.75	46.25	>47.00
Select RZD	0.500	0.500	0.500	0.525	0.550	0.550	0.550	0.575	0.575
Select LZA	-31	-32	-33	-33	-33	-34	-34	-34	-35

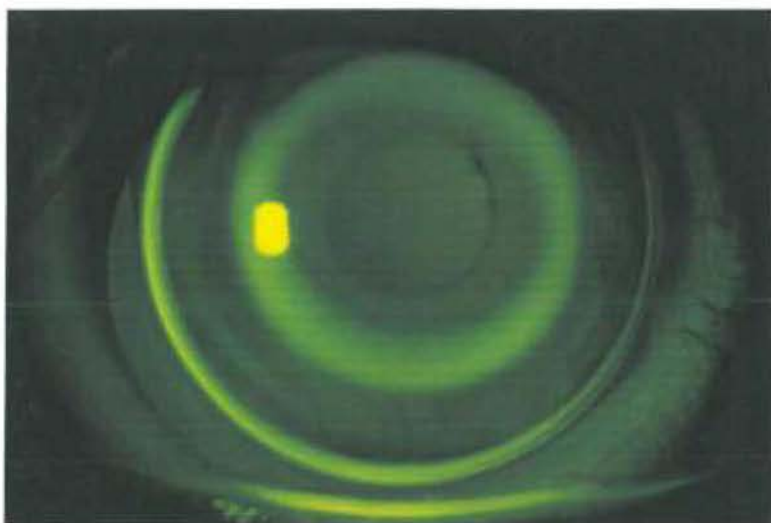
In the previous figure the Flat "K" was 44.50 and the vertexed spherical power to correct was -4.50 sphere. The CRT Calculator determined that a lens with a base curve of 8.60 mm (39.25 D.) would be required. The tray containing the nine 8.60 mm lenses is removed from the Diagnostic Dispensing System. The Calculator has determined the initial diagnostic lens to place on the eye has the parameters listed in the following figure.

Diagnostic Dispensing Set 8.60 mm 39.25D

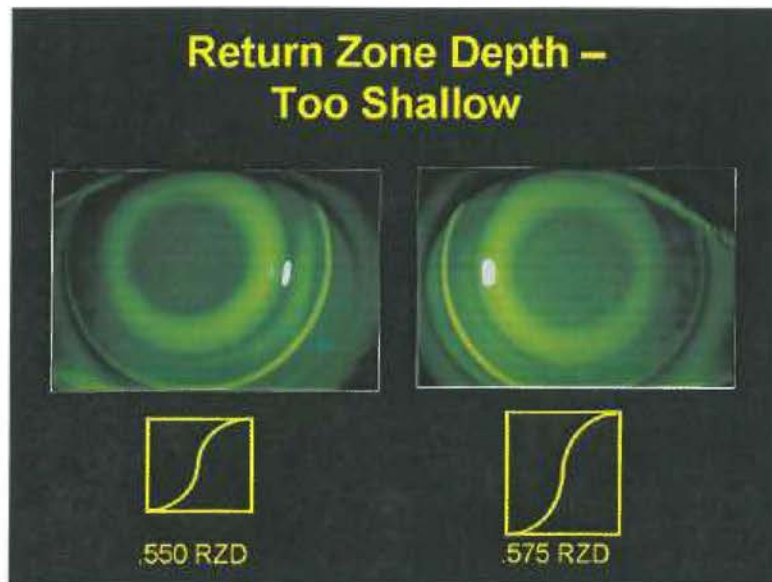
Deeper ↑ Sagittal Depth ↓ Shallower	8.60 .575 RZD -32 angle	8.60 .575 RZD -33 angle	8.60 .575 RZD -34 angle
	8.60 .550 RZD -32 angle	Initial Lens 8.60 .550 RZD -33 angle	8.60 .550 RZD -34 angle
	8.60 .525 RZD -32 angle	8.60 .525 RZD -33 angle	8.60 .525 RZD -34 angle
		- Angle Degree +	

Step #2 The Initial Diagnostic Lens

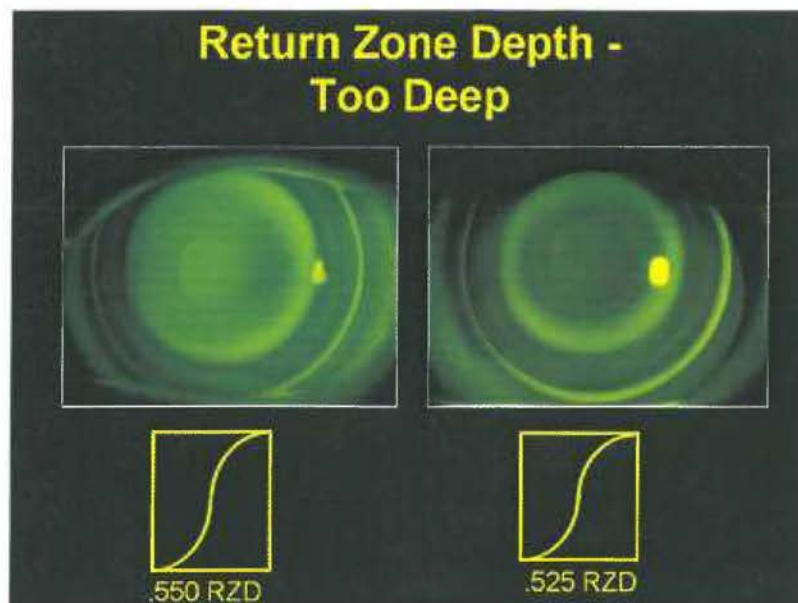
The 8.60 base curve lens with a Return Zone Depth of .550 and a Landing Zone Angle of 33 is placed on the eye and evaluated with fluorescein. The initial diagnostic lens is considered acceptable if the lens provides centration over the pupil, a 4 mm area of central treatment and adequate alignment in the peripheral cornea.



If the initial diagnostic lens should decenter, the lens with the next steeper Return Zone Depth is placed on the eye and evaluated. In this case the .575 RZD is selected.

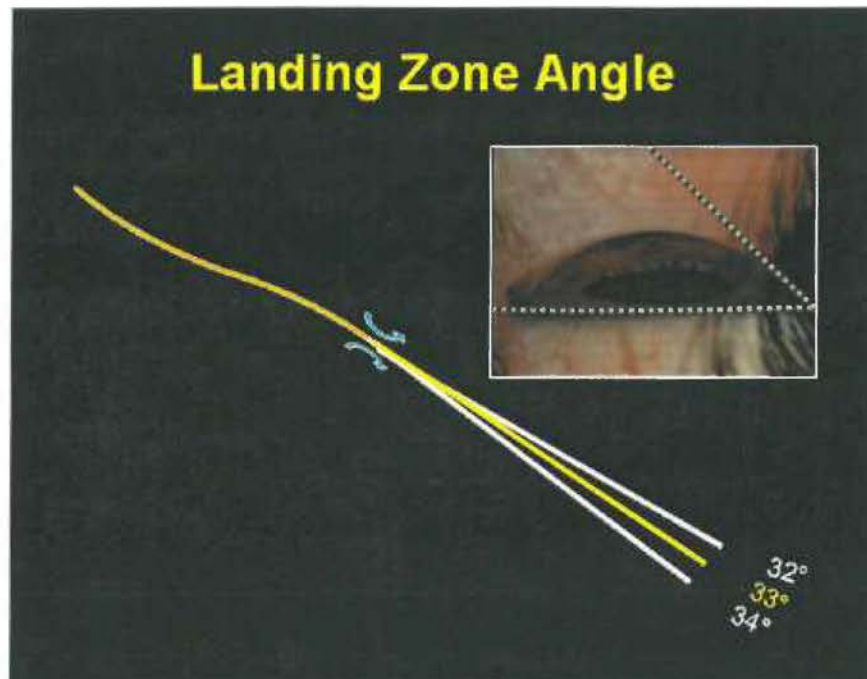


If the initial diagnostic lens exhibits excessive apical clearance, the Return Zone Depth can be decreased thereby bring the base curve into closer apposition to the cornea.

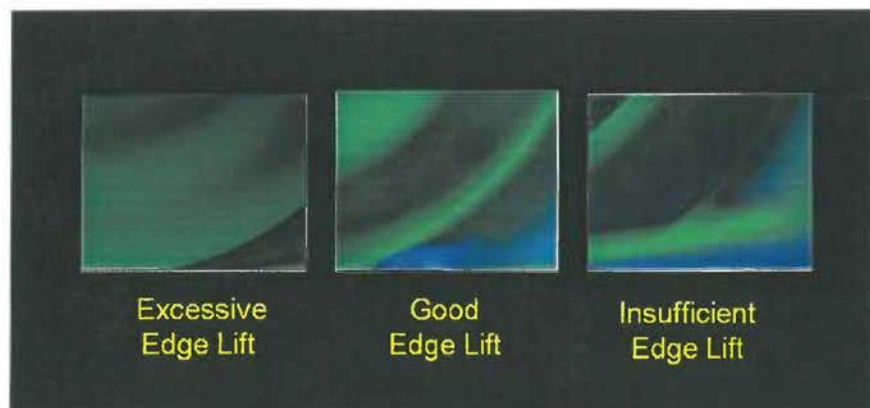


Step #3 Evaluation of the Peripheral Landing Zone Angle

As previously stated, the Paragon CRT Lens incorporates a unique Tangent Angle in the lens periphery. The function of the angle is to provide a gentle facilitate lens movement and centration on the eye. The angles within the diagnostic set are provided in degrees of 32, 33 and 34.



Once the appropriate Return Zone Depth has been established, the Landing Zone Angle can be easily evaluated with fluorescein.



Goal of the Study

The goal of this study is to determine the success rate of the initial suggested CRT diagnostic lens projected by the Paragon CRT Calculator.

Methods

We split our study into two parts. For the first part, the subjects were all optometry students and were -1.00D to -4.00D myope with less than -2.00D of astigmatism. The only difference between part one and two was that part one involved 9 subjects and only fit each subject with one diagnostic lens in their right eye. This study was done to fine tune our procedures, discover problem areas, and set up video recording equipment. It was not designed nor intended to be submitted to analysis.

The second part was the focus of the study. All 30 subjects were optometry students and were selected on their refractive error. All subjects were -1.00D to -4.00D myope with less than -2.00D of astigmatism. Each subject had a keratometer reading taken with a Humphrey Atlas Topographer before insertion of the Paragon CRT Lens. Based on each subject's refractive error and flat K (according to the Humphrey Atlas Topographer), the Paragon CRT Calculator suggested an initial diagnostic lens.

The study was designed to fit each subject with nine different lenses in their right eye. Treatment of each lens before insertion was to clean thoroughly with the Boston RGP cleaner, rinse with Renu multi-purpose solution, and condition with Unique pH. Before the very first lens was inserted, one drop of proparacaine 0.5% was instilled in the right eye. The first lens inserted was always the initial diagnostic lens suggested by the CRT Calculator. Fluorescein was instilled after each lens was inserted and viewed under a slit lamp with a cobalt blue filter.

The other eight lenses were selected on these parameters relative to the diagnostic lens:

1. Same BC, 0.025 steeper RZD, 1° flatter LZA
2. Same BC, 0.025 steeper RZD, same LZA
3. Same BC, 0.025 steeper RZD, 1° steeper LZA
4. Same BC, same RZD, 1° flatter LZA
5. Same BC, same RZD, 1° steeper LZA
6. Same BC, 0.025 flatter RZD, 1° flatter LZA
7. Same BC, 0.025 flatter RZD, same LZA
8. Same BC, 0.025 flatter RZD, 1° steeper LZA

In the case of when one or more of these eight lenses were not available, the unavailable lenses were not included in the study. After the removal of each lens, the treatment consisted of Boston RGP cleaner, rinse with Renu multi-purpose solution, condition with Unique pH, and then it was placed back in its container. Each lens fit was video recorded for approximately 15 seconds under the slit lamp and was reviewed and analyzed after all the subjects had been recorded.

Results

The results from this study will be combined with those from the New England College of Optometry and Southern College of Optometry to create a new nomogram for selecting the most appropriate CRT diagnostic lens. Due to the classified nature of the study, the sponsor Paragon Vision Sciences has requested the work remain proprietary until the spring of 2003. At that time the study results and conclusion will be added to the thesis in the form of an addendum.